Summary Public Assessment Report

Generics

Escitalopram Medreg
escitalopram

SK/H/0292/001/DC

Date: 11/2023

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escitalopram, film-coated tablets, 10 mg

This is a summary of the public assessment report (PAR) for Escitalopram Medreg. It explains how Escitalopram Medreg was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Escitalopram Medreg.

For practical information about using Escitalopram Medreg, patients should read the package leaflet or contact their doctor or pharmacist.

What is Escitalopram Medreg and what is it used for?

Escitalopram Medreg is a 'generic medicine'. This means that Escitalopram Medreg is similar to a 'reference medicine' already authorised in the European Union (EU) called Cipralex.
Escitalopram Medreg is used in the treatment of depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram Medreg, even if it takes some time before you feel any improvement in your condition.

How does Escitalopram Medreg work?

Escitalopram Medreg contains the active substance escitalopram. Escitalopram Medreg belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level.

How is Escitalopram Medreg used?

The pharmaceutical form of Escitalopram Medreg is film-coated tablets and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Escitalopram Medreg have been shown in studies?

Because Escitalopram Medreg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Cipralex. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Escitalopram Medreg?

Because Escitalopram Medreg is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Escitalopram Medreg approved?

It was concluded that, in accordance with EU requirements, Escitalopram Medreg has been shown to be comparable to Cipralex. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Cipralex, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Escitalopram Medreg?

A risk management plan has been developed to ensure that Escitalopram Medreg is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Escitalopram Medreg, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Escitalopram Medreg

The marketing authorisation for Escitalopram Medreg was granted on 15 November 2023.

The full PAR for Escitalopram Medreg can be found on the website. For more information about treatment with Escitalopram Medreg, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 11-2023.